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410-795-7365

Cut and Post for future reference.



Bioterrorism Newsletter

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National Laboratory Response Network for Bioterrorism

The use of a biological agent for terrorism is a low probability event with very large, potentially devastating consequences. It is important that we be prepared to minimize the consequences. There are two types of bioterrorism events, **covert event** and **overt event**. A **covert event** occurs without prior warning, patients usually fall ill or die from causes of unknown or unusual origin, the causative agent is undetermined, and clinical laboratories are crucial in isolating and identifying the biological agent in cooperation with the Public Health Laboratory. An **overt event** is announced, patients fall ill or die, the biological agent is confirmed in clinical cases only, and hoaxes are assumed to be real.

A Laboratory Response Network has been established to provide rapid response and immediate identification of the biological agent. Clinical laboratories are the essential part of this Network and represent early responders for cases occurring in patients. Public health laboratories are involved in bioterrorism by congressional mandate, because of experience with biological agents and their role in outbreak investigations. They represent the link between local laboratories and the CDC and federal agencies.

In bioterrorism, early detection and identification of the agent and its source by the public health laboratory are crucial for minimizing the potentially catastrophic human and economic costs of an attack. A clinical laboratory may be a first responder in a covert bioterrorism event and the laboratory will have a critical role to play as part of the State's Laboratory Response Network. A member of the Laboratory Response Network at the Florida State Public Health Laboratory diagnosed the first case of inhalation anthrax. However, 6 cases of cutaneous anthrax that occurred in New York and New Jersey between September 29th and October 1st, 2001, were undiagnosed and went unreported because of its infrequent occurrence. Unfortunately, there is a lack of familiarity

in the clinical laboratory with uncommon infections. Diseases that might be used by a bioterrorist are uncommon; there is little incentive for industry to develop diagnostic tests, that are FDA approved, for these agents .

In the case of anthrax, the clinical laboratory should not consider unidentified grampositive bacilli growing on agar as a contaminant but it should be treated as a "finding" when it occurs in a suspicious clinical setting (e.g., febrile illness in a previously healthy person). If the clinical laboratory cannot rule-out anthrax, the culture should be sent to the State Public Health Laboratory without delay.

The Association of Public Health Laboratories (APHL) and the CDC established the Laboratory Response Network (LRN). The LRN is composed of four levels of laboratories to participate in routine disease surveillance activities. These levels have been designated A, B, C and D based on their capacity to conduct various levels

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National Laboratory Response Network

Continued

of identification of bioterrorism agents. Most of the Level A laboratories are hospital and other clinical laboratories that participate in the LRN. Level A laboratories either rule out or refer critical agents encountered in their routine to a Level B or C laboratory (Public Health Laboratory). Level C laboratories are public health laboratories where biosafety level 3 facilities are available. Level C laboratories can perform all the tests of a Level B laboratory as well as nucleic acid amplification detection of critical agents and handle anthrax spore containing powders. Level B and C laboratories use standard protocols and reagents for identification of specific agents.

Level D laboratories are large federal laboratories (CDC, USAMRIID) which have biosafety level 4 facilities to handle highly infectious agents with high fatality (Ebola and Variola major). They also are capable of identifying agents referred by Level B and C laboratories, identify genetic recombinant microbes not recognizable by conventional isolation and identification methods.

The Laboratory Response Network (LRN) for bioterrorism are primarily public and private laboratories that test according to consensus protocols with timely and accurate testing and reporting. These laboratories are linked with Local, State and federal agencies.

Levels of LRN laboratories and their characteristics are the following:

BT Level A: Clinical Laboratories

Use BSL-2 safety facilities, assess risk for aerosols, detect early presumptive cases. Rule-out or refer isolates to state public health laboratory.

BT Level B: Public Health Laboratories

BSL-3 facility performs susceptibility testing, isolate and identify agent. Rule-in and refer to

Level C laboratory.

BT Level C: Public Health Laboratories

BSL-3 facility, rapid identification of agents,

rule-in and refer to Level D laboratory.

BT Level D: CDC and USAMRID

BSL-4 facility, archive, perform high-level characterization probes for a universe of agents,

gene sequencing.

Level A laboratories should have a BT plan. If there is an announced threat, the FBI should be notified immediately as well as the Public Health Laboratory. Then, based on consultation, test and/or refer specimens. If unannounced but suspected, rule-out or refer isolate. If unable to rule-out, call the State Public Health Laboratory about the case and submit specimens. Level A laboratories should keep their plan updated, periodically test the plan, provide training to their staff, know who to call, know shipping requirements and chain-of-custody requirements, and review current laboratory protocols and practices.

Information is included in this issue of the *Bioterrorism Newsletter* to assist clinical laboratories in preparing their protocols. ❖

Biological Diseases/ Agents Listing

(September 5, 2002)

Category A

- Anthrax (Bacillus anthracis)
- Botulism (*Clostridium botuli-num* toxin)
- Plague (*Yersinia pestis*)
- Smallpox (variola major)
- Tularemia (Francisella tularensis)
- Viral hemorrhagic fevers (filoviruses [e.g., Ebola, Marburg] and arenaviruses [e.g., Lassa, Machupo])

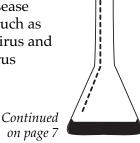
Category B

- Brucellosis (Brucella species
- Epsilon toxin of *Clostridium perfringens*
- Food safety threats (e.g., Salmonella species, Escherichia coli 0157:H7, Shigella)
- Glanders (Burkholderia mallei)
- Melioidosis (*Burkholderia* pseudomallei)
- Psittacosis (*Chlamydia psittaci*)
- Q fever (Coxiella burnetii)
- Ricin toxin from *Ricinus communis* (castor beans)
- Staphylococcal enterotoxin B
- Typhus fever (*Rickettsia prowazekii*)
- Viral encephalitis

 (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis])
- Water safety threats (e.g., Vibrio cholerae, Cryptosporidium parvum)

Category C

 Emerging infectious disease threats such as Nipah virus and hantavirus



Category Descriptions

Category A Diseases/Agents

The U.S. public health system and primary healthcare providers must be prepared to address various biological agents, including pathogens that are rarely seen in the United States.

High-priority agents include organisms that pose a risk to national security because they:

- can be easily disseminated or transmitted from person to person;
- result in high mortality rates and have the potential for major public health impact;
- might cause public panic and social disruption; and
- require special action for public health preparedness.

Category B Diseases/Agents

Second highest priority agents include those that:

- are moderately easy to disseminate;
- result in moderate morbidity rates and low mortality rates; and
- require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance.

Category C Diseases/Agents

Third highest priority agents include emerging pathogens that could be engineered for mass dissemination in the future because of:

- availability;
- ease of producttion and dissemination; and
- potential for high morbidity and mortality rates and major health impact. 愛

PACKAGING and TRANSPORTING PROTOCOL

Packaging and labeling specimens is the same as for any infectious substance

- If the specimen is a dry powder or paper material, place it in a plastic zip-lock bag, place biohazard label, and follow steps 1-4 (see diagram below).
- If the specimen is a clinical specimen, place biohazard label on the specimen receptacle, wrap the receptacle with an absorbent material, and follow steps 1-4 (see diagram).
 - 1. Place the bag or specimen receptacle into a leak proof container with a tight cover that is labeled "biohazard".
 - 2. Place this container into a second leak proof container with a tight cover that is labeled "biohazard". The size of the second container should be no larger than a one-gallon paint can.
 - For a clinical specimen, an ice pack (not ice) should be placed in the second container to keep the specimen cold.
 - If the specimen is not a clinical specimen, but is paper or powder, the ice pack should be omitted.
 - 3. Place the second container into a third leak proof container with a tight cover that is labeled "biohazard". The third container should be no larger than a five-gallon paint can.
 - 4. Both containers should meet state and federal regulations for transport of hazardous material, and be properly labeled.

